STATE OF _____

DEPARTMENT OF _____

CHAPTER 100A-1, ADMINISTRATIVE CODE

CERTIFICATION OF ENVIRONMENTAL TESTING LABORATORIES

100A-1.001 Policy and Incorporated Reference Materials.

(1) The responsibility of ensuring the availability of safe drinking water to the people of the state of _____ and of limiting hazardous discharges that contaminate the air, water, and ground resources of the state has been entrusted to the Department of _____ through _____(various regulations citations)_____.

(2) The availability of laboratories capable of performing reliable analyses is an essential factor in conducting a successful environmental monitoring program.

(3) The Department of _____ has been given the responsibility, pursuant to _____(regulations)___, for ensuring the acceptable quality, reliability and validity of test results from environmental samples through establishing criteria for laboratories to be certified to perform such analysis.

(4) Analysis of drinking water samples from all the water supply systems in the state may require the utilization of laboratories other than the state public health laboratories. Data provided by laboratories other than those certified by the

United States Environmental Protection Agency (US EPA) can be accepted only after such laboratories have been evaluated and certified by the principal state laboratory, which has been certified by the US EPA.

(5) Laboratories seeking certification to perform analyses of environmental samples shall satisfy the minimum criteria expressed in this Rule Chapter.

(6) The purpose of these Rules is to provide regulations for the evaluation and certification of laboratories seeking to analyze environmental samples to satisfy the requirements of _____(regulations)_____.

(7) Having established such criteria for evaluation and certification, the Department of _____ has been delegated as the Accrediting Authority for the State of _____ and has the responsibility for implementing and administering such laboratory certification, pursuant to _____(regulations)_____.

(8) If any section, subsection, provision, clause, or portion of this chapter is adjudged unconstitutional or invalid by a court of competent jurisdiction or in any proceeding, the remainder of this chapter shall not be affected thereby.

(9) The approved and recommended sample collection procedures, analytical methodologies, and certification requirements are contained in the following documents, which are adopted herein by reference into these Rules:

(a) "National Environmental Laboratory Accreditation Conference - Constitution, Bylaws, and Standards," July 2, 1998, incorporated by reference into Rules 100A-1.002(11), 100A-1.005(11), and 100A-1.017(5).

Section 1.8.1 and Figure 1-3 of this document are incorporated by reference into Rule 100A-1.002(10).

Sections 1.8.3 and 4.1.1 of this document are incorporated by reference into Rules 100A-1.002(13) and 100A-1.005(1).

Section 1.8.4 of this document is incorporated by reference into Rule 100A-1.005(2).

Sections 1.8.5 through 1.8.10 of this document are incorporated by reference into Rule 100A-1.005(3).

Chapter 2 of this document is incorporated by reference into Rule 100A-1.008(1).

Sections 2.4, 2.5, and 2.7 of this document are incorporated by reference into Rule 100A-1.008(9).

Section 3.3 of this document is incorporated by reference into Rule 100A-1.010(5).

Sections 3.4 through 3.7 of this document are incorporated by reference into Rule 100A-1.010(4).

Sections 4.1.4(d) and 4.4 of this document are incorporated by reference into Rules 100A-1.014(1)(u) and 100A-1.016.

Sections 4.1.7 and 4.1.9 of this document are incorporated by reference into Rule 100A-1.006(1).

Sections 4.1.8 and 4.3.2 of this document are incorporated by reference into Rule 100A-1.006(3).

Section 4.3.3 of this document is incorporated by reference into Rule 100A-1.011(5).

Chapter 5 of this document is incorporated by reference into Rules 100A-1.005(1), 100A-1.010(7), and 100A-1.013(1).

Section 5.5 of this document is incorporated by reference into Rule 100A-1.009(2).

Section 5.13 of this document is incorporated by reference into Rule 100A-1.013(3).

Section 5.14 of this document is incorporated by reference into Rule 64E-1.013(4).

Chapter 5, Appendix A of this document is incorporated by reference into Rule 100A-1.002.

Chapter 5, Appendix D of this document is incorporated by reference into Rules 100A-1.005(3) and 100A-1.013(1).

Chapter 5, Appendix E of this document is incorporated by reference into Rules 100A-1.003(4)(d) and 100A-1.003(4)(f).

(b) Appendices A through J to Title 40 Code of Federal Regulations (40 CFR) Part 50, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(a) and 100A-1.005(11).

(c) Appendices M and P to 40 CFR Part 51, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(a), 100A-1.005(4)(a), 100A-1.005(11), and 100A-1.009(2).

(d) Appendices D and E to 40 CFR Part 52, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(a) and 100A-1.005(11).

(e) Subparts B, C, and D to 40 CFR Part 53, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(b), 100A-1.005(4)(a), 100A-1.005(4)(c), 100A-1.005(11), and 100A-1.009(2).

(f) 40 CFR Parts 57.305 and 57.404, both revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(4)(e) and 100A-1.009(2).

(g) Appendices A and B to 40 CFR Part 58, revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(4)(c) and 100A-1.009(2).

(h) Appendices A, B, and F to 40 CFR Part 60, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(a), 100A-1.005(4)(a), 100A-1.005(11), and 100A-1.009(2).

(i) Appendix B to 40 CFR Part 61, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(a) and 100A-1.005(11).

(j) 40 CFR Parts 63.7 through 63.10, revised as 7-1-97, incorporated by reference into Rules 100A-1.005(4)(b) and 100A-1.009(2).

(k) Appendices A and C to 40 CFR Part 63, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(a) and 100A-1.005(11). Method 301 in Appendix A is incorporated by reference into Rule 100A-1.003(4)(b).

(l) Subparts F and G to 40 CFR Part 75, revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(4)(d) and 100A-1.009(2).

(m) Appendices A, B, D, E, and G to 40 CFR Part 75, revised as of 7-1-97. Appendices A and B are incorporated by reference into Rules 100A-1.005(4)(d) and 100A-1.009(2). Appendices D, E, and G are incorporated by reference into Rules 100A-1.003(4)(a) and 100A-1.005(11).

(n) 40 CFR Parts 79.57 and 79.60 through 79.68, all revised as of 7-1-97. Part 79.57 is incorporated by reference into Rules 100A-1.005(4)(g) and 100A-1.009(2). Parts 79.60 and 79.61 are incorporated by reference into Rules 100A-1.005(4)(f) and 100A-1.009(2). Parts 79.61 through 79.68 are incorporated by reference into Rules 100A-1.003(4)(a) and 100A-1.005(11).

(o) 40 CFR Parts 80.46(g), 80.55, and 80.56, all revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(a) and 100A-1.005(11).

(p) Appendices A, B, E, and F to 40 CFR Part 80, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(a) and 100A-1.005(11).

(q) Appendix A to 40 CFR Part 82, Subpart F, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(a) and 100A-1.005(11).

(r) 40 CFR Parts 122.21(g)(7) and 122.21(h)(4), revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(5)(a) and 100A-1.009(2).

(s) 40 CFR Parts 136.3 and 136.4, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(c), 100A-1.003(4)(d), 100A-1.005(5)(b), 100A-1.005(11), and 100A-1.009(2).

(t) Appendices A through D to 40 CFR Part 136, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(c) and 100A-1.005(11). Appendix B is incorporated by reference into Rules 100A-1.005(5)(b) and 100A-1.009(2).

(u) Federal Register, Volume 62, page 48393 (62 FR 48393), 9-15-97, incorporated by reference into Rules 100A-1.003(4)(c) and 100A-1.005(11).

(v) 40 CFR Parts 141.21(c) and (f), 141.23(k), 141.24(e), 141.24(f)(17) and (20), 141.24(h)(13) and (19), 141.25, 141.27, 141.30(e), 141.40(g), 141.40(n)(11) and (12), 141.74(a), 141.86(b), 141.89, 141.142(b), and 141.143(b), all revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(e), 100A-1.003(4)(f), 100A-1.005(6)(a), 100A-1.005(6)(b), 100A-1.005(11), and 100A-1.009(2).

(w) 40 CFR Part 143.4(b), revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(e) and 100A-1.005(11).

(x) 40 CFR Part 146.68(a), revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(8)(d) and 100A-1.009(2).

(y) 40 CFR Part 158.190 and Subpart D to 40 CFR Part 158, both revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(g) and 100A-1.005(11).

(z) 40 CFR Part 160, revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(7) and 100A-1.009(2).

(aa) 40 CFR Part 257.23(a), revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(8)(a) and 100A-1.009(2).

(ab) 40 CFR Part 258.53(a), revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(8)(a) and 100A-1.009(2).

(ac) 40 CFR Parts 260.11 and 260.21, both revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(h), 100A-1.003(4)(i), and 100A-1.005(11).

(ad) Appendix I to 40 CFR Part 261, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(h) and 100A-1.005(11).

(ae) 40 CFR Parts 264.13, 264.97(d) and (e), 264.278(e), 264.1033(e)(1), 264.1034, and 264.1063, all revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(8)(b), 100A-1.005(8)(e), and 100A-1.009(2).

(af) 40 CFR Parts 265.13, 265.92(a), 265.1033(e)(1), 265.1034, 265.1063, and 265.1084, all revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(8)(b), 100A-1.005(8)(c), 100A-1.005(8)(e), and 100A-1.009(2).

(ag) 62 FR 64636, 12-8-97, incorporated by reference into Rules 100A-1.005(8)(c) and 100A-1.009(2).

(ah) 40 CFR Parts 266.100(c)(1)(ii), 266.100(f)(2), 266.102(b), 266.104(e)(1), 266.106(g), 266.107(f), and

266.112(b), all revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(i), 100A-1.005(8)(f), 100A-1.005(11), and 100A-1.009(2).

(ai) Appendix IX to 40 CFR Part 266, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(h) and 100A-1.005(11).

(aj) 40 CFR Parts 268.7(a)(1), 268.7(b)(1), and 268.40(f), all revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(8)(a) and 100A-1.009(2).

(ak) 40 CFR Parts 270.19(c)(1)(iii), 270.22(a)(2)(ii)(B), 270.62(b)(2)(i)(C), and 270.66(c)(2)(i), all revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(8)(g) and 100A-1.009(2).

(al) 40 CFR Parts 279.10(b)(1)(ii), 279.44(c), 279.53(c), 279.55, and 279.63(c), all revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(8)(h) and 100A-1.009(2).

(am) 40 CFR Parts 300.415(b)(4)(ii), 300.420(c)(4), 300.430(b)(8), 300.915(a)(9), 300.915(a)(11), and 300.915(a)(12), all revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(j), 100A-1.005(9), 100A-1.005(11), and 100A-1.009(2).

(an) Appendix C to 40 CFR Part 300, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(j) and 100A-1.005(11).

(ao) 40 CFR Parts 403.7(b)(2), 403.12(b)(5), and 403.12(g)(4), all revised as of 7-1-97, incorporated by reference

into Rules 100A-1.003(4)(d), 100A-1.005(5)(a), 100A-1.005(5)(b), 100A-1.005(11), and 100A-1.009(2).

(ap) Appendix E to 40 CFR Part 403, revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(5)(a) and 100A-1.009(2).

(aq) Appendices A and B to 40 CFR Part 425, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(c) and 100A-1.005(11).

(ar) 40 CFR Part 434.64, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(c) and 100A-1.005(11).

(as) Appendices 1 and 2 to 40 CFR Part 435, Subpart A, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(c) and 100A-1.005(11).

(at) 40 CFR Part 455.50, revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(5)(b) and 100A-1.009(2).

(au) Table 7 to 40 CFR Part 455, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(c) and 100A-1.005(11).

(av) 40 CFR Part 465.03(c), revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(c) and 100A-1.005(11).

(aw) 40 CFR Part 501.15(b)(10)(iv), revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(5)(c) and 100A-1.009(2).

(ax) 40 CFR Part 503.8, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(c), 100A-1.005(5)(c), 100A-1.005(11), and 100A-1.009(2).

(ay) 40 CFR Part 761.19, 761.60(a)(3)(iii)(B)(6), and 761.75(b)(6)(iii), all revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(k), 100A-1.005(10)(b), 100A-1.005(11), and 100A-1.009(2).

(az) 40 CFR Parts 763.87(b), 763.90(i)(3) and (4), and 763.121(f)(5), all revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(k), 100A-1.005(10)(c), 100A-1.005(11), and 100A-1.009(2).

(ba) Appendices A and E to 40 CFR Part 763, Subpart E, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(k) and 100A-1.005(11).

(bb) Appendices A and B to 40 CFR Part 763.121, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(k) and 100A-1.005(11).

(bc) 40 CFR Parts 766.12 through 766.18, revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(10)(a) and 100A-1.009(2).

(bd) 40 CFR Part 792, revised as of 7-1-97, incorporated by reference into Rules 100A-1.005(10) and 100A-1.009(2).

(be) 40 CFR Part 795, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(k) and 100A-1.005(11).

(bf) 40 CFR Part 796, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(k) and 100A-1.005(11).

(bg) 40 CFR Part 797, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(k) and 100A-1.005(11).

(bh) 40 CFR Part 798, revised as of 7-1-97, incorporated by reference into Rules 100A-1.003(4)(k) and 100A-1.005(11).

(bi) "Standard Methods for the Examination of Water and Wastewater," 18th Edition, American Public Health Association, American Water Works Association, Water Pollution Control Federation, 1991, incorporated by reference into Rules 100A-1.003(4)(c), 100A-1.003(4)(e), and 100A-1.005(11).

(bj) "Methods for the Chemical Analysis of Water and Wastes," EPA-600/4-79-020, revised March 1983, incorporated by reference into Rules 100A-1.003(4)(c), 100A-1.003(4)(e), and 100A-1.005(11).

(bk) "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," November 1986; Update I, July 1992; Update II, September 1994; Update IIA, August 1993; Update IIB, January 1995; and Update III, December 1996; SW-846, 3rd Edition, Volumes 1A-1C and 2, incorporated by reference into Rules 100A-1.003(4)(h) and 100A-1.005(11).

(bl) "Annual Book of ASTM Standards," Section 5 - Petroleum Products, Lubricants, and Fossil Fuels, and Section 11 - Water and Environmental Technology, American Society for

Testing and Materials, 1994, incorporated by reference into Rules 100A-1.003(4)(a), 100A-1.003(4)(c), 100A-1.003(4)(e), 100A-1.003(4)(h), and 100A-1.005(11).

(bm) "Methods for the Determination of Metals in Environmental Samples," EPA/600/4-91/010, June 1991, incorporated by reference into Rules 100A-1.003(4)(c), 100A-1.003(4)(e), and 100A-1.005(11).

(bn) "Methods for the Determination of Metals in Environmental Samples - Supplement I," EPA/600/R-94/111, May 1994, incorporated by reference into Rules 100A-1.003(4)(c), 100A-1.003(4)(e), and 100A-1.005(11).

(bo) "Methods for the Determination of Inorganic Substances in Environmental Samples," EPA-600/R-93-100, August 1993, incorporated by reference into Rules 100A-1.003(4)(c), 100A-1.003(4)(e), and 100A-1.005(11).

(bp) "Methods for the Determination of Organic Compounds in Drinking Water," EPA/600/4-88/039, revised July 1991, incorporated by reference into Rules 100A-1.003(4)(e) and 100A-1.005(11).

(bq) "Methods for the Determination of Organic Compounds in Drinking Water, Supplement I," EPA/600/4-90/020, July 1990, incorporated by reference into Rules 100A-1.003(4)(e) and 100A-1.005(11).

(br) "Methods for the Determination of Organic Compounds in Drinking Water, Supplement II," EPA/600/R-92/129, August 1992, incorporated by reference into Rules 100A-1.003(4)(e) and 100A-1.005(11).

(bs) "Methods for the Determination of Organic Compounds in Drinking Water, Supplement III," EPA/600/R-95/131, August 1995, incorporated by reference into Rules 100A-1.003(4)(e) and 100A-1.005(11).

(bt) EPA Method 1613, "Tetra- through Octa-Chlorinated Dioxins and Furans by Isotope Dilution HRGC/HRMS," Revision B, EPA 821-B-94-005, October 1994, incorporated by reference into Rules 100A-1.003(4)(e) and 100A-1.005(11).

(bu) "Methods for the Determination of Nonconventional Pesticides in Municipal and Industrial Waters," Volume I, EPA-821-R-93-010-A, August 1993, Revision 1, incorporated by reference into Rules 100A-1.003(4)(c) and 100A-1.005(11).

(bv) EPA Method 100.1, "Analytical Method for Determination of Asbestos Fibers in Water," EPA-600/4-83-043, September 1983, incorporated by reference into Rules 100A-1.003(4)(e) and 100A-1.005(11).

(bw) EPA Method 100.2, "Determination of Asbestos Structures over 10 μm in Length in Drinking Water," EPA/600/R-94/134, June 1994, incorporated by reference into Rules 100A-1.003(4)(e) and 100A-1.005(11).

(bx) "Test Methods for Escherichia Coli in Drinking Water," EPA/600/4-91/016, July 1991, incorporated by reference into Rules 100A-1.003(4)(e) and 100A-1.005(11).

(by) "Consensus Method for Determining Groundwaters Under the Direct Influence of Surface Water Using Microscopic Particulate Analysis (MPA)," EPA 910/9-92-029, October 1992,

incorporated by reference into Rules 100A-1.003(4)(e) and 100A-1.005(11).

(bz) "ICR Sampling Manual," EPA 814-B-96-001, April 1996, incorporated by reference into Rules 100A-1.003(4)(e) and 100A-1.005(11).

(ca) "DBP/ICR Analytical Methods Manual," EPA 814-B-96-002, April 1996, incorporated by reference into Rules 100A-1.003(4)(e) and 100A-1.005(11).

(cb) "ICR Microbial Laboratory Manual," EPA 600/R-95/178, April 1996, incorporated by reference into Rules 100A-1.003(4)(e) and 100A-1.005(11).

(cc) "EPA Method 1600: Membrane Filter Test Method for Enterococci in Water," EPA-821-R-97-004, May 1997, incorporated by reference into Rules 100A-1.003(4)(c) and 100A-1.005(11).

(cd) "Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms," EPA/600/4-90/027F, August 1993, incorporated by reference into Rules 100A-1.003(4)(c) and 100A-1.005(11).

(ce) "Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms," EPA/600/4-91/002, July 1994, 3rd Edition, incorporated by reference into Rules 100A-1.003(4)(c) and 100A-1.005(11).

(cf) "Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms," EPA/600/4-91/003, July 1994, 2nd Edition,

incorporated by reference into Rules 100A-1.003(4)(c) and 100A-1.005(11).

(cg) "Interim Radiochemical Methodology for Drinking Water," EPA 600/4-75-008 (Revised), March 1976, incorporated by reference into Rules 100A-1.003(4)(e) and 100A-1.005(11).

(ch) "Prescribed Procedures for Measurement of Radioactivity in Drinking Water," EPA-600/4-80-032, August 1980, icorporated by reference into Rules 100A-1.003(4)(e) and 100A-1.005(11).

(ci) "Manual for the Certification of Laboratories Analyzing Drinking Water, Criteria and Procedures, Quality Assurance," 4th Edition, EPA 815-B-97-001, March 1997, incorporated by reference into Rules 100A-1.002(11), 100A-1.002(13), 100A-1.003(4)(e), and 100A-1.005(11).

(cj) "Technical Notes on Drinking Water Methods," EPA-600/R-94-173, October 1994, incorporated by reference into Rules 100A-1.003(4)(e) and 100A-1.005(11).

(ck) 63 FR 18504, 4-15-98, incorporated by reference into Rules 100A-1.003(4)(c) and 100A-1.005(11).

(cl) "US EPA Contract Laboratory Program - Statement of Work for Organics Analysis," Document OLM01.0 plus Revisions OLM01.1, December 1990; OLM01.2, January 1991; OLM01.3, February 1991; OLM01.4, March 1991; OLM01.5, April 1991; and OLM01.6, June 1991; incorporated by reference into Rules 100A-1.003(4)(h) and 100A-1.005(11).

(cm) "US EPA Contract Laboratory Program - Statement of Work for Inorganics Analysis," Document ILM02.0, incorporated by reference into Rules 100A-1.003(4)(h) and 100A-1.005(11).

(cn) "Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air," EPA/600/4-89/017, June 1988, incorporated by reference into Rules 100A-1.003(4)(a) and 100A-1.005(11).

(co) "Compendium of Methods for the Determination of Air Pollutants in Indoor Air," EPA/600/4-90/010, April 1990, incorporated by reference into Rules 100A-1.003(4)(a) and 100A-1.005(11).

(cp) "EPA Field Methods Compendium (FMC) Draft," OERR #9285.2-11, July 1993, incorporated by reference into Rules 100A-1.003(4)(h) and 100A-1.005(11).

(cq) "Requirements for Nationwide Approval of New and Optionally Revised Methods for Inorganic and Organic Parameters in National Primary Drinking Water Regulations Monitoring," Revision 1.0, July 7, 1992, incorporated by reference into Rules 100A-1.003(4)(f) and 100A-1.005(11).

(cr) "Requirements for Nationwide Approval of New or Optionally Revised Methods for Total Coliforms, Fecal Coliforms, and/or E. Coli, in National Drinking Water Monitoring," Revision 1.2, June 30, 1992, incorporated by reference into Rules 100A-1.003(4)(f) and 100A-1.005(11).

(cs) "Guidance on the Evaluation of Safe Drinking Water Act Compliance Monitoring Results from Performance-Based

Methods," EPA Draft, January 14, 1994, incorporated by reference into Rules 100A-1.003(4)(f) and 100A-1.005(11).

(ct) "Guidelines Establishing Test Procedures for the Analysis of Pollutants: Flexibility in Existing Test Procedures and Streamlined Approach for Approving New Test Methods," 62 FR 14975, 3-28-97, incorporated by reference into Rules 100A-1.003(4)(d) and 100A-1.005(11).

(cu) "Performance Based Measurement System," 62 FR 52098, 10-6-97, incorporated by reference into Rules 100A-1.003(4)(d) and 100A-1.005(11).

` (cv) ISO Guide 25, "General Requirements for the Competence of Calibration and Testing Laboratories," 1990, incorporated by reference into Rule 100A-1.005(1).

(cw) "National Environmental Laboratory Accreditation Program Analyte Sheet," Form _____, __(revision date)__, incorporated by reference into Rule 100A-1.012(2).

(cx) "Application for Certification of Environmental Testing Laboratories," Form _____, __(revision date)__, incorporated by reference into Rules 100A-1.006(1) and 100A-1.007(2)(b).

(cy) "NELAP Testing Laboratory Certificate," Form _____, __(revision date)__, incorporated by reference into Rule 100A-1.012(1).

(cz) "Renewal Attestation of Compliance," Form _____, __(revision date)__, incorporated by reference into Rule 100A-1.011(1).

(da) "Environmental Testing Laboratory Renewal Invoice," Form _____, __(revision date)__, incorporated by reference into Rule 100A-1.011(1).

(db) "Statement of Deficiencies and Plan of Correction," Form _____, __(revision date)__, incorporated by reference into Rules 100A-1.010(8) and 100A-1.014(1)(n).

(dc) "Technical Evaluation Criteria for Accreditation of Emission Testing Organizations (EPA Methods 1 through 5 and Associated Methods)," Roy F. Weston Inc., October 30, 1992, incorporated by reference into Rule 100A-1.010(4).

(dd) "Handbook for Analytical Quality Control in Water and Wastewater Laboratories," EPA/600/4-79/019, March 1979, incorporated by reference into Rule 100A-1.010(4).

(de) "EPA Method 1664: N-Hexane Extractable Material (HEM) and Silica Gel Treated N-Hexane Extractable Material (SGT-TEM) by Extraction and Gravimetry (Oil and Grease and Total Petroleum Hydrocarbons)," EPA-821-B-94-004b, April 1995, incorporated by reference into Rules 100A-1.003(4)(c) and 100A-1.005(11).

(df) EPA Document 2185, "Good Automated Laboratory Practices," 1995 Edition, 8/10/95.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.002 Definitions.

In addition to the definitions set forth in ____(State regulations)____ and in Chapter 5, Appendix A of the National Environmental Laboratory Accreditation Conference (NELAC) Standards, adopted by reference herein, as used in this Rule, the following terms shall mean:

(1) EPA - means the United States Environmental Protection Agency.

(2) (a) Environmental Sample - means a sample from any natural source, or a source that reasonably may be expected to contribute pollution to or receive pollution from the atmosphere, drinking water supplies, groundwaters, surface waters, soils and sediments, or ecosystem biota of the state.

(b) This environmental sample includes, for example: ambient air, air emissions from point sources, drinking water, receiving waters, waters used to define natural background conditions, soils, sediments, industrial, domestic, or municipal discharge effluents, samples from chemical storage or handling facilities, waste disposal facilities or areas, and industrial or agricultural chemical handling or application areas (such as hazardous waste), surface water runoff, and samples from facilities for handling or applying of chemicals for weed or insect control.

(3) Principal State Laboratory - means the central laboratory that has been certified by the US EPA for performance of chemical, microbiological, and radiochemical analyses of

drinking water and is responsible for certification of all other local laboratories for performance of such analyses required under the Safe Drinking Water Act.

(4) Approved Testing Methods - means the laboratory or field procedures in Tier IV that have been approved for testing environmental samples and that shall be required for certification under these rules.

(5) Field Testing - means the sampling, analysis, or other testing operation occurring in the same premises as where the environmental sample is obtained.

(6) Certification - means regulatory recognition given to a local laboratory that performs analyses pursuant to various environmental monitoring regulations, meets minimum analytical performance standards, and meets other requirements as set forth in this Rule.

(7) Decertification - means revocation or suspension of certification for one or more of the reasons indicated in Rule 100A-1.014.

(8) Recertification - means reinstatement of certification following correction of the deficiencies for which the laboratory was decertified.

(9) Renewal - means reissuing of certification to a local laboratory.

(10) Category of Certification - means the collection and organization within successive tiers of testing as defined in Section 1.8.1 and Figure 1-3 of the NELAC Standards, which are adopted by reference herein. The laboratory must select at least

one method and analyte from Tiers IV and V in Rule 100A-1.003, in order to attain certification that is nationally recognized. The categories are organized such that the Department of _____ may collect fees sufficient to meet the costs of administering the certification program and may administer the certification criteria as consistently, efficiently, and inexpensively as possible.

(11) NELAC Standards - means the concensus standards developed for testing laboratory performance and accrediting authority decisions, adopted at the National Environmental Laboratory Accreditation Conference on July 2, 1998 and adopted by reference herein.

(12) Analyte - means the particular compound, element, radical, isotope, characteristic, contaminant, mixture, organism, species, or condition for which the environmental sample is being tested.

(13) Technical Director - means the responsible party of record qualified according to Section 4.1.1 of the NELAC Standards, adopted herein by reference, or a chemist, microbiologist, physicist or professional scientist qualified by academic training and experience as stated in the "Manual for the Certification of Laboratories Analyzing Drinking Water, Criteria and Procedures, Quality Assurance," 4th Edition, EPA 815-B-97-001, March 1997, also adopted herein by reference, to administer the technical and scientific operations of the laboratory, including the supervising of testing procedures and reporting of results.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.003 Scope of Accreditation.

Under the NELAC Standards, the tiers of laboratory testing and field sampling are described below. The first tiers contain more general requirements for accreditation, and each successive tier contains additional requirements to demonstrate capability in more specific fields of sampling or testing.

(1) Tier I: Legal Identity and Mission

(a) Laboratory Testing

(b) Field Sampling

(2) Tier II: Testing Capability - the general scientific discipline of testing within each business Mission identified in Tier I.

(a) Chemistry

(b) Microbiology

(c) Whole Effluent Toxicity

(d) Radiochemistry

(e) Field Measurement

(f) Microscopy

(3) Tier III: Regulatory Program - the sampling and testing protocols and Quality Assurance procedures for each Testing Capability identified in Tier II, which are required for

compliance with the specified environmental monitoring regulations. The following Regulatory Programs are addressed:

(a) Clean Air Act (CAA) - Title 40 Code of Federal Regulations Parts 50 through 99 (40 CFR Parts 50 through 99).

(b) Clean Water Act (CWA) - 40 CFR Parts 100 through 140 and Parts 400 through 599.

(c) Safe Drinking Water Act (SDWA) - 40 CFR Parts 141 through 149.

(d) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) - 40 CFR Parts 150 through 189.

(e) Resource Conservation and Recovery Act (RCRA) - 40 CFR Parts 240 through 299.

(f) Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - 40 CFR Parts 300 through 399.

(g) Toxic Substances Control Act (TSCA) - 40 CFR Parts 700 through 799.

(h) STATE SUPPLEMENTAL CERTIFICATION: _____

_____

(4) Tier IV: Test Methods - the approved laboratory testing procedures within the Regulatory Programs identified in Tier III, as follows:

(a) CAA - The approved test methods are found in:

1. Appendices A through J of Title 40, Code of Federal Regulations (40 CFR) Part 50, revised as of 7-1-97,

2. Appendix M to 40 CFR Part 51, revised as of 7-1-97,

3. Appendices D and E to 40 CFR Part 52, revised as of 7-1-97,

4. Appendices A and B to 40 CFR Part 60, revised as of 7-1-97,

5. Appendix B to 40 CFR Part 61, revised as of 7-1-97,

6. Appendices A and C to 40 CFR Part 63, revised as of 7-1-97,

7. Appendices D, E, and G to 40 CFR Part 75, revised as of 7-1-97,

8. 40 CFR Parts 79.61 through 79.68, revised as of 7-1-97,

9. 40 CFR Parts 80.46(g), 80.55, 80.56, and Appendices A, B, E, and F to 40 CFR Part 80, revised as of 7-1-97,

10. Appendix A to 40 CFR Part 82, Subpart F, revised as of 7-1-97,

11. "Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air," EPA/600/4-89/017, June 1988,

12. "Compendium of Methods for the Determination of Air Pollutants in Indoor Air," EPA/600/4-90/010, April 1990, and

13. "Annual Book of ASTM Standards," Section 5 - Petroleum Products, Lubricants, and Fossil Fuels, American Society for Testing and Materials, 1994.

Each of these documents is adopted by reference herein.

(b) Alternate test methods for CAA must be documented, evaluated, and determined to be equivalent in performance to the approved reference methods, according to the procedures and criteria in 40 CFR Part 53, Subparts B, C, and D, revised as of 7-1-97, which are also adopted by reference herein. If no validated test method is available, alternate test methods must be documented and validated according to the criteria in Method 301, found in Appendix A to 40 CFR Part 63, revised as of 7-1-97 and adopted herein by reference.

(c) CWA - The approved test methods are found or referenced in:

1. 40 CFR Part 136.3 and Appendices A, C, and D to 40 CFR Part 136, revised as of 7-1-97 and amended in Volume 62 of the Federal Register, beginning at page 48393 (62 FR 48393), September 15, 1997,

2. Appendices A and B to 40 CFR Part 425, revised as of 7-1-97,

3. 40 CFR Part 434.64, revised as of 7-1-97,

4. Appendices 1 and 2 to 40 CFR Part 435, Subpart A, revised as of 7-1-97,

5. Table 7 to 40 CFR Part 455, revised on 7-1-97,

6. 40 CFR Part 465.03(c), revised as of 7-1-97,

7. 40 CFR Part 503.8, revised as of 7-1-97,

8. "Methods for Chemical Analysis of Water and Wastes," EPA-600/4-79-020, revised March 1983,

9. "Standard Methods for the Examination of Water and Wastewater," 18th Edition, American Public Health Association, American Water Works Association, Water Pollution Control Federation, 1991,

10. "Methods for the Determination of Metals in Environmental Samples," EPA/600/4-91/010, June 1991,

11. "Methods for the Determination of Metals in Environmental Samples, Supplement I," EPA/600/R-94/111, May 1994,

12. "Methods for the Determination of Nonconventional Pesticides in Municipal and Industrial Waters," Volume I, EPA-821-R-93-010-A, August 1993, Revision 1,

13. "Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms," EPA/600/4-90/027F, August 1993,

14. "Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms," EPA/600/4-91/002, July 1994, 3rd Edition,

15. "Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms," EPA/600/4-91/003, July 1994, 2nd Edition,

16. "Annual Book of ASTM Standards," Section 5 - Petroleum Products, Lubricants, and Fossil Fuels, and Section 11 - Water and Environmental Technology, American Society for Testing and Materials, 1994,

17. 63 FR 18504, April 15, 1998,

18. "Methods for the Determination of Inorganic Substances in Environmental Samples," EPA-600/R-93-100, August 1993,

19. "EPA Method 1600: Membrane Filter Test Method for Enterococci in Water," EPA-821-R-97-004, May 1997, and

20. "EPA Method 1664: N-Hexane Extractable Material (HEM) and Silica Gel Treated N-Hexane Extractable Material (SGT-TEM) by Extraction and Gravimetry (Oil and Grease and Total Petroleum Hydrocarbons)," EPA-821-B-94-004b, April 1995.

All of these documents are incorporated by reference into this Rule.

(d) Performance-based alternate test methods for CWA may be acceptable if the laboratory receives EPA approval for the alternate method according to 40 CFR Parts 403.7(b)(2)(v), 403.12(b)(5)(vi), or 403.12(g)(4), all revised as of 7-1-97 and adopted by reference herein. Additionally, an alternate test method may be acceptable if the laboratory fulfills application requirements in 40 CFR Part 136.4, revised as of 7-1-97 and adopted by reference herein, and if the proposed method is

documented and evaluated to meet the same performance criteria as the referenced methods, according to the procedures and criteria in:

1. Chapter 5, Appendix E of the NELAC Standards, revised as of July 2, 1998,

2. "Guidelines Establishing Test Procedures for the Analysis of Pollutants: Flexibility in Existing Test Procedures and Streamlined Approach for Approving New Test Methods," 62 FR 14975, March 28, 1997, or

3. "Performance Based Measurement System," 62 FR 52098, October 6, 1997,

which are all adopted herein by reference.

(e) SDWA - The approved test methods are found or referenced in:

1. 40 CFR Parts 141.21(f), 141.23(k)(1), 141.24(e), 141.25(a) and (b), 141.40(n)(11), 141.74(a), 141.142(b), and 141.143(b), all revised as of 7-1-97,

2. 40 CFR Part 143.4(b), revised as of 7-1-97,

3. "Methods for the Determination of Organic Compounds in Drinking Water," EPA/600/4-88/039, revised July 1991,

4. "Methods for the Determination of Organic Compounds in Drinking Water, Supplement I," EPA/600/4-90/020, July 1990,

5. "Methods for the Determination of Organic Compounds in Drinking Water, Supplement II," EPA/600/R-92/129, August 1992,

6. "Test Methods for *Escherichia Coli* in Drinking Water," EPA/600/4-91/016, July 1991,

7. "Methods for Chemical Analysis of Water and Wastes," EPA-600/4-79-020, revised March 1983.

8. "Standard Methods for the Examination of Water and Wastewater," 18th Edition, American Public Health Association, American Water Works Association, Water Pollution Control Federation, 1991,

9. "Consensus Method for Determining Groundwaters Under the Direct Influence of Surface Water Using Microscopic Particulate Analysis (MPA)," EPA 910/9-92-029, October 1992,

10. "Methods for the Determination of Organic Compounds in Drinking Water, Supplement III," EPA/600/R-95/131, August 1995,

11. EPA Method 1613, "Tetra- through Octa-Chlorinated Dioxins and Furans by Isotope Dilution HRGC/HRMS," Revision B, EPA 821-B-94-005, October 1994,

12. "Methods for the Determination of Metals in Environmental Samples," EPA/600/4-91/010, June 1991,

13. "Methods for the Determination of Metals in Environmental Samples, Supplement I," EPA/600/R-94/111, May 1994,

14. "Interim Radiochemical Methodology for Drinking Water," EPA 600/4-75-008 (Revised), March 1976,

15. "Prescribed Procedures for Measurement of Radioactivity in Drinking Water," EPA-600/4-80-032, August 1980,

16. "Annual Book of ASTM Standards," Section 5 - Petroleum Products, Lubricants, and Fossil Fuels, and Section 11 - Water and Environmental Technology, American Society for Testing and Materials, 1994,

17. "Methods for the Determination of Inorganic Substances in Environmental Samples," EPA-600/R-93-100, August 1993,

18. EPA Method 100.1, "Analytical Method for Determination of Asbestos Fibers in Water," EPA-600/4-83-043, September 1983,

19. EPA Method 100.2, "Determination of Asbestos Structures Over 10-μm in Length in Drinking Water," EPA/600/R-94/134, June 1994,

20. "Technical Notes on Drinking Water Methods," EPA-600/R-94-173, October 1994,

21. "Manual for the Certification of Laboratories Analyzing Drinking Water, Criteria and Procedures, Quality Assurance," 4th Edition, EPA 815-B-97-001, March 1997,

22. "ICR Sampling Manual," EPA 814-B-96-001, April 1996,

23. "DBP/ICR Analytical Methods Manual," EPA 814-B-96-002, April 1996, and

24. "ICR Microbial Laboratory Manual," EPA 600/R-95/178, April 1996.

Each of these documents is incorporated by reference into this Rule.

(f) Alternate test methods for SDWA may be used if they are documented; evaluated for satisfactory performance according to:

1. Chapter 5, Appendix E of the NELAC Standards, revised as of July 2, 1998,

2. "Requirements for Nationwide Approval of New and Optionally Revised Methods for Inorganic and Organic Parameters in National Primary Drinking Water Regulations Monitoring," Revision 1.0, July 7, 1992,

3. "Requirements for Nationwide Approval of New or Optionally Revised Methods for Total Coliforms, Fecal Coliforms, and/or *E. Coli*, in National Drinking Water Monitoring," Revision 1.2, June 30, 1992,

4. "Guidance on the Evaluation of Safe Drinking Water Act Compliance Monitoring Results from Performance-Based Methods," EPA Draft, January 14, 1994, or

5. 40 CFR Part 141.27, revised as of 7-1-97;

and listed in the Federal Register as equally effective to the approved test methods. Each of these documents is adopted by reference herein.

(g) FIFRA - The required testing is referenced in 40 CFR Part 158.190 and in 40 CFR Part 158, Subpart D, both revised as of 7-1-97 and adopted by reference herein.

(h) RCRA - The approved test methods are referenced or found in:

1. 40 CFR Part 260.11, revised as of 7-1-97,

2. Appendix I to 40 CFR Part 261, revised as of 7-1-97,

3. Appendix IX to 40 CFR Part 266, revised as of 7-1-97,

4. "Annual Book of ASTM Standards," Section 5 - Petroleum Products, Lubricants, and Fossil Fuels, American Society for Testing and Materials, 1994,

5. "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," November 1986; Update I, July 1992; Update II, September 1994; Update IIA, August 1993; Update IIB, January 1995; and Update III, December 1996; SW-846, 3rd Edition, Volumes 1A-1C and 2,

6. "US EPA Contract Laboratory Program - Statement of Work for Organics Analysis," Document OLM01.0 plus Revisions OLM01.1, December 1990; OLM01.2, January 1991; OLM01.3, February 1991; OLM01.4, March 1991; OLM01.5, April 1991; and OLM01.6, June 1991,

7. "US EPA Contract Laboratory Program - Statement of Work for Inorganics Analysis," Document ILM02.0, and

8. "EPA Field Methods Compendium (FMC) Draft," OERR #9285.2-11, July 1993.

Each document is incorporated by reference into this Rule. Only the current promulgated test methods for SW-846, as given in the Methods Status Table (5/97) in the SW-846 Manual, are available for certification.

(i) To use an alternate test method for RCRA, a laboratory must petition and receive EPA approval for a regulatory amendment to add the equivalent testing method, as stipulated in 40 CFR Part 260.21, revised as of 7-1-97 and adopted herein by reference. Alternate test methods that meet or exceed the performance capabilities of SW-846 methods may be used for compliance testing associated with boilers and industrial furnaces, according to 40 CFR Parts 266.100(c)(1)(ii), 266.100(f)(2), and 266.102(b), all revised as of 7-1-97 and adopted by reference herein.

(j) CERCLA - The approved test methods are referenced in 40 CFR Parts 300.915(a)(9), 300.915(a)(11), and Appendix C to Part 300, which are revised as of 7-1-97 and incorporated herein by reference.

(k) TSCA - The approved testing procedures are found in:

1. 40 CFR Part 761.19, revised as of 7-1-97,

2. Appendices A and E to 40 CFR Part 763, Subpart E and Appendices A and B to 40 CFR Part 763.121, all revised as of 7-1-97,

3. 40 CFR Part 795, revised as of 7-1-97,

4. 40 CFR Part 796, revised as of 7-1-97,

5. 40 CFR Part 797, revised as of 7-1-97, and

6. 40 CFR Part 798, revised as of 7-1-97,

which are all adopted by reference herein. Alternate, equivalent methods for testing ambient air for Asbestos may be acceptable if these methods fulfill the criteria in 40 CFR Part

763.121(f)(5)(iii), revised as of 7-1-97 and adopted by reference herein.

(l) STATE SUPPLEMENTAL CERTIFICATION: _____

_____

(5) Tier V: Analytes - the specific contaminants within each Test Method identified in Tier IV, which are determined in order to assess process efficacy, environmental or health impacts, regulatory compliance, or the general condition of defined systems. The analyte must be listed in the approved test method, for a testing laboratory to be certified for the analyte with that method.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.004 Categories of Certification.

(State Accrediting Authorities may need to define different combinations of Tier III, Tier IV, and Tier V Scope of Accreditation as their categories of certification, in order to apportion the available resources most effectively in meeting the workload requirements for the certification process, and to assess the appropriate certification fees equitably)_____

_____

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.005 Laboratory Certification Criteria.

(1) To be certified for Laboratory Testing (Tier I), a laboratory shall meet the general requirements specified in the following NELAC Standards:

Section 1.8.3 - General Laboratory Requirements

Section 4.1.1 - Personnel Qualification

Section 5.0 - Introduction

Section 5.1 - Scope (of Quality System)

Section 5.4 - Organization and Management

Section 5.5 - Quality System

Section 5.6 - Personnel

Section 5.7 - Physical Facilities

Section 5.8 - Equipment and Reference Materials

Section 5.9 - Measurement Traceability and Calibration

Section 5.10 - Test Methods and Standard Operating Procedures

Section 5.11 - Sample Handling, Acceptance Policy, and Receipt

Section 5.12 - Records

Section 5.13 - Report Format and Contents

Section 5.14 - Subcontracting Samples

Section 5.15 - Outside Support Services and Supplies

Section 5.16 - Complaints

The above NELAC Standards are adopted by reference herein and patterned after ISO Guide 25, which is also adopted by reference herein.

(2) To be certified for Field Sampling (Tier I), a laboratory must meet the requirements specified in Section 1.8.4 of the NELAC Standards, which is adopted herein by reference.

(3) To be certified for the Chemistry, Whole Effluent Toxicity, Microbiology, Microscopy, Radiochemistry, or Field Measurement Testing Capabilities (Tier II), a laboratory shall meet the requirements specified in the following NELAC Standards, adopted herein by reference:

(a) Section 1.8.5 and Chapter 5, Appendix D.1 for Chemistry testing.

(b) Section 1.8.6 and Chapter 5, Appendix D.2 for Whole Effluent Toxicity testing.

(c) Section 1.8.7 and Chapter 5, Appendix D.3 for Microbiology testing.

(d) Section 1.8.8 and Chapter 5, Appendix D.4 for Radiochemistry testing.

(e) Section 1.8.9 for Microscopy testing.

(f) Section 1.8.10 for Field Measurement testing.

(4) To be certified under the CAA Regulatory Program (Tier III):

(a) A laboratory supporting continuous emissions monitors for source gas emissions must comply with the testing performance characteristics in 40 CFR Part 53, Subparts B and D, revised as of 7-1-97 and adopted by reference herein, and with

quality assurance requirements and objectives in Appendix F to 40 CFR Part 60 and in Appendix P to 40 CFR Part 61, both revised as of 7-1-97 and adopted herein by reference.

(b) If the continuous emissions monitors are for stationary sources emitting hazardous air pollutants, the laboratory shall comply with performance testing, monitoring, notification, recordkeeping, and reporting requirements in 40 CFR Parts 63.7 through 63.10, revised as of 7-1-97 and adopted by reference herein.

(c) Laboratories supporting ambient air monitoring systems must comply with testing performance characteristics in 40 CFR Part 53, Subparts B and D, revised as of 7-1-97, and with the reporting and quality assurance requirements in Appendix A to 40 CFR Part 58, revised as of 7-1-97, for state and local air monitoring stations, and in Appendix B to 40 CFR Part 58, revised as of 7-1-97, for air stations that support Prevention of Significant Deterioration (PSD) permit monitoring. Each of these CFR references are adopted by reference herein.

(d) If the laboratory supports continuous emissions monitors for acid rain permits, the laboratory shall comply with recordkeeping, reporting, performance testing, and quality assurance requirements in 40 CFR Part 75, Subparts F and G, and in Appendices A and B to 40 CFR Part 75, all revised as of 7-1-97 and adopted by reference herein.

(e) Laboratories supporting continuous emissions monitors for primary nonferrous smelter orders (NSO) must fulfill

the requirements in 40 CFR Parts 57.305 and 57.404, revised as of 7-1-97 and adopted herein by reference.

(f) A laboratory supporting registration of a fuel or fuel additive shall comply with the Good Laboratory Practice standards, reporting requirements, and other quality assurance requirements in 40 CFR Parts 79.60 and 79.61, both revised as of 7-1-97 and adopted by reference herein.

(g) A field sampling organization supporting fuel and fuel additive registrations shall comply with the emissions generation requirements in 40 CFR Part 79.57, revised as of 7-1-97 and adopted by reference herein.

(5) To be certified under the CWA Regulatory Program (Tier III):

(a) A field sampling organization must comply with the sampling protocols specified in 40 CFR Parts 122.21(g)(7) and 122.21(h)(4), both revised as of 7-1-97 and adopted by reference herein. A field sampling organization supporting pretreatment regulations for industrial users must comply with sampling protocols in 40 CFR Parts 403.7(b)(2), 403.12(b)(5), 403.12(g)(4), and Appendix E to Part 403, all revised as of 7-1-97 and adopted herein by reference.

(b) Laboratories must comply with sample container, holding times, preservation, and method detection limit requirements in 40 CFR Part 136.3(e) and Appendix B to 40 CFR Part 136, revised as of 7-1-97 and adopted herein by reference. A laboratory supporting pretreatment regulations must comply with analytical requirements in 40 CFR Parts 403.7(b)(2),

403.12(b)(5), and 403.12(g)(4), all revised as of 7-1-97 and adopted by reference herein. A laboratory testing for pesticide active ingredients must comply with the methodology requirements in 40 CFR Part 455.50, revised as of 7-1-97 and adopted by reference herein.

(c) Laboratories and field sampling organizations that test sewage sludges must collect representative samples and comply with methodology requirements in 40 CFR Parts 501.15(b)(10)(iv) and 503.8, both revised as of 7-1-97 and adopted by reference herein.

(6) To be certified under the SDWA Regulatory Program (Tier III):

(a) A laboratory must comply with method detection limit, sample container, holding time, proficiency, testing according to approved methods, and other quality assurance requirements in 40 CFR Parts 141.21(c), 141.21(f), 141.23(k), 141.24(e), 141.24(f)(17) and (20), 141.24(h)(13) and (19), 141.25, 141.30(e), 141.40(g), 141.40(n)(11) and (12), 141.74(a), and 141.89, all revised as of 7-1-97 and adopted by reference herein.

(b) Field sampling organizations must collect tap water samples for Lead and Copper according to the requirements in 40 CFR Part 141.86(b), revised as of 7-1-97 and adopted by reference herein.

(7) To be certified under the FIFRA Regulatory Program (Tier III), the laboratory or field sampling organization must

comply with the Good Laboratory Practice standards in 40 CFR Part 160, revised as of 7-1-97 and adopted by reference herein.

(8) To be certified under the RCRA Regulatory Program (Tier III):

(a) A laboratory or field sampling organization that supports a solid waste disposal facility or a municipal solid waste landfill must comply with documented groundwater monitoring program requirements for sampling, preservation and transport, analysis, chain-of-custody, and quality assurance and quality control, as stipulated in 40 CFR Parts 257.23(a) and 258.53(a), both revised as of 7-1-97 and herein adopted by reference. Testing of solid waste to determine whether it is prohibited from land disposal must conform to methodology requirements in 40 CFR Parts 268.7(a)(1), 268.7(b)(1), and 268.40(f), all revised as of 7-1-97 and incorporated herein by reference.

(b) A laboratory supporting a hazardous waste facility must comply with sampling, preservation and transport, analysis, and chain-of-custody requirements documented in waste analysis plans, as specified in 40 CFR Parts 264.13 and 265.13; groundwater monitoring plans, as specified in 40 CFR Parts 264.97(d)-(e) and 265.92(a); and, if applicable, soil and soil-pore liquid monitoring, as specified in 40 CFR Part 264.278(e). Each of these CFR references are revised as of 7-1-97 and adopted herein by reference.

(c) Laboratories and field sampling organizations performing waste testing to determine compliance with air emissions standards from tanks, surface impoundments, and

containers shall comply with sampling and analysis requirements in 40 CFR Part 265.1084, revised as of 7-1-97 and amended at 62 FR 64636, December 8, 1997, both adopted by reference herein.

(d) Laboratories and field sampling organizations supporting an Underground Injection Control program for hazardous waste must comply with documented procedures approved in a written waste analysis plan, as referenced in 40 CFR Part 146.68(a), revised as of 7-1-97 and adopted by reference herein.

(e) Laboratories and field sampling organizations performing testing to ensure compliance with air emissions standards for process vents and equipment leaks must comply with methodology requirements in 40 CFR Parts 264.1033(e)(1), 264.1034, 264.1063, 265.1033(e)(1), 265.1034, and 265.1063, all revised as of 7-1-97 and adopted herein by reference.

(f) Laboratories and field sampling organizations that perform sampling and analysis of hazardous waste burned in boilers and industrial furnaces must comply with methodology requirements in 40 CFR Parts 266.100(c)(1)(ii), 266.100(f)(2), 266.102(b), 266.104(e)(1), 266.106(g), 266.107(f), and 266.112(b), all revised as or 7-1-97 and adopted by reference herein.

(g) Laboratories and field sampling organizations performing waste analysis for hazardous waste permits and trial burn plans for incinerators, boilers, and industrial furnaces shall comply with the methodology requirements in 40 CFR Parts 270.19(c)(1)(iii), 270.22(a)(2)(ii)(B), 270.62(b)(2)(i)(C), and

270.66(c)(2)(i), all revised as of 7-1-97 and adopted by reference herein.

(h) Laboratories and field sampling organizations supporting used oil processing and re-refining facilities must meet requirements for representative sampling and analytical methodology in 40 CFR Parts 279.10(b)(1)(ii), 279.44(c), 279.53(c), 279.55, and 279.63(c), all revised as of 7-1-97 and adopted herein by reference, in order to prove that the used oil is not hazardous.

(9) To be certified under the CERCLA Regulatory Program (Tier III), a laboratory or field sampling organization that supports a potential Superfund site, or generates data in support of remedial investigation, feasibility studies, or remedy selection for mitigating pollutant releases from that site, shall comply with documented field sampling and quality assurance project plan requirements as referenced in 40 CFR Parts 300.415(b)(4)(ii), 300.420(c)(4), and 300.430(b)(8), all revised as of 7-1-97 and adopted by reference herein. Laboratories supplying technical product data for dispersants and other chemicals shall comply with the requirements in 40 CFR Part 300.915(a)(12), revised as of 7-1-97 and adopted by reference herein.

(10) To be certified under the TSCA Regulatory Program (Tier III), a laboratory shall comply with the Good Laboratory Practice standards in 40 CFR Part 792, revised as of 7-1-97 and adopted by reference herein.

(a) A laboratory certified for Dibenzo-p-dioxins and Dibenzofurans in this Program must also comply with the method development and study protocol requirements in 40 CFR Parts 766.12 through 766.18, revised as of 7-1-97 and adopted herein by reference.

(b) Laboratories and field sampling organizations that test for Polychlorinated Biphenyls must comply with methodology requirements in 40 CFR Part 761.60(g), revised as of 7-1-97 and adopted by reference herein, for sampling and with analytical methodology requirements in 40 CFR Parts 761.60(a)(3)(iii)(B)(6) and 761.75(b)(6)(iii), both revised as of 7-1-97 and adopted by reference herein.

(c) Laboratories and field sampling organizations that test for Asbestos must comply with air sampling methodology requirements specified in 40 CFR Part 763.121(f)(5)(i) and with applicable analysis method requirements in 40 CFR Parts 763.87(b), 763.90(i)(3) and (4), and 763.121(f)(5)(ii), all revised as of 7-1-97 and adopted by reference herein.

(11) To be certified for specific approved Test Methods (Tier IV), the laboratory shall comply with the requirements in each approved test method and the corresponding NELAC Standards. The NELAC Standards shall take precedence in those cases where conflicting requirements exist. The laboratory shall also comply with the manufacturer’s instructions for maintaining and tuning each test equipment, optimizing test performance, and demonstrating measurement system performance. However, the corresponding test methods and NELAC Standards take precedence

and shall be followed where conflicts exist. All approved Test Methods and NELAC Standards, plus provisions for allowing the use of Alternate Test Procedures or Performance-Based Measurement Systems, are contained within the documents cited in Rule 100A-1.003 and adopted herein by reference.

(12) A laboratory using an Alternate Test Procedure or Performance-Based Measurement System in Tier IV shall submit to the Department of _____ a written copy of the alternate test method prior to the on-site inspection of that laboratory. An alternate test method can be approved only if it is equivalent to or better than the approved Test Method in meeting defined objectives for accuracy, precision, completeness, and comparability, in relation to determining compliance with any regulatory concentration levels or system conditions, or if no approved Test Method is available for the requested sample analysis. Use of alternate methods may require written approval from EPA or publication in the Federal Register.

(13) To be certified for specific Analytes (Tier V) within each approved Test Method, the laboratory shall comply with the test method requirements and corresponding NELAC Standards for initial and on-going test equipment calibrations and analyst demonstrations of precision, accuracy, and sensitivity for each analyte. The NELAC Standards shall take precedence in those cases where conflicting requirements exist. A laboratory shall comply with the provisions in Subsection (12) above for an approved test method in which the laboratory adds analytes to the element or compound list validated in the method.

(14) The lack of requirements for analytical testing to be performed only by laboratories certified pursuant to these Rules does not diminish or negate requirements in other Rules regarding personnel, methodology, proficiency testing, quality assurance, or other requirements for data acceptability as promulgated therein.

(15) STATE SUPPLEMENTAL CRITERIA: _____
_____

Specific Authority: _____
Law Implemented: _____
History: New _____

100D-1.006 Certification Requirements.

(1) An application for certification shall be made in writing to the Department of _____ on Form _____, accompanied by the application fee, and shall contain at least the information listed in Sections 4.1.7 and 4.1.9 of the NELAC Standards, adopted by reference herein. Form _____, "Application for Accreditation of Environmental Testing Laboratories under NELAP," __(revision date)__ is also adopted by reference herein.

(2) Separate application and certification shall be required for all laboratories maintained on separate premises even though operated under the same management; however, separate certification is not required for separate buildings on the same

or adjoining grounds or for a mobile laboratory that is performing the same testing for analytes and methods as certified at the fixed laboratory and is away from the fixed laboratory for less than 90 calendar days.

(3) The laboratory shall report in writing to the Department of _____ within 30 days all changes in laboratory name, ownership, location, personnel, methodology or any other factor consistent with the information in Sections 4.1.8 and 4.3.2 of the NELAC Standards, adopted herein by reference, that significantly affect the performance of analyses for which the laboratory was originally certified.

(4) Not withstanding any other errors or omissions, an application is not completed until the laboratory has fulfilled all of the following requirements:

(a) The application reviewed by the Department of _____ was found to request approved test methods as required in Rule 100A-1.003.

(b) Proficiency samples are successfully analyzed, if available, from a NELAP-approved proficiency test sample provider, as required in Rule 100A-1.008.

(c) A written Quality Manual has been prepared as required in Rule 100A-1.009.

(d) An on-site laboratory inspection has been conducted for the test methods and analytes for which the laboratory is seeking certification, as required in Rule 100A-1.010.

(e) Certification fees are paid as required in Rule 100A-1.017.

(f) The laboratory's Technical Director or Directors were found to be qualified according to Rule 100A-1.002(13).

(g) The laboratory responds in writing to each deficiency noted in the on-site inspection report with an acceptable plan of correction and completion date, as required in Rule 100A-1.010.

(5) Applications for certification not completed within 2 years from the date received by the Department of _____ shall expire, and certification shall be denied.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.007 Certification of Out-of-State Laboratories.

(1) The Department of _____ may certify an out-of-state laboratory to perform environmental sample analyses provided that the laboratory complies with all the requirements in this Rule.

(2) An out-of-state laboratory may be eligible for reciprocal certification to perform environmental sample analyses provided:

(a) The laboratory is certified by a state recognized as a NELAP Accrediting Authority for those scientific disciplines and regulatory programs in which the laboratory is requesting certification pursuant to this Rule.

(b) The laboratory submits to the Department of _____ an application on Form _____, which is adopted herein by reference, copies of the laboratory's three most recent proficiency test results demonstrating compliance with Rule 100A-1.008, and the fees required by Rule 100A-1.017.

(c) The laboratory complies with the requirements of Rule 100A-1.005, and

(d) The laboratory submits to the Department of _____ a copy of its most recent (less than 2 years old) on-site inspection report from the Accrediting Authority or from the Accrediting Authority’s delegated Assessor Body, together with a current copy of the laboratory's certification; a listing of the categories, analytes, and test methods certified; and the Accrediting Authority's rules and regulations regarding laboratory certification.

(3) If upon review of the documents listed in section (2) above the Department of _____ determines that the out-of-state certification program is equivalent to the requirements of this Rule, the Department of _____ will not require an on-site survey by its inspectors and certification may be granted after the assessed certification fees are paid.

(4) If upon review of the documents listed in section (2) above the Department of _____ is unable to determine that the out-of-state certification program is equivalent to the requirements of this Rule, then, in addition to the requirements in paragraphs (2)(b) and (2)(c) above, the

Department of _____ shall conduct an on-site inspection of the laboratory. The laboratory will be responsible for the cost of the on-site inspection.

(a) The Department of _____ may grant certification if the results of the inspection verify compliance with this Rule and after the invoiced certification fees and on-site inspection expenses are paid.

(b) If the results of the on-site survey do not indicate the laboratory's compliance with the requirements of this Rule, the laboratory's application for certification will be denied.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.008 Proficiency Testing Requirements.

(1) Applicant and certified laboratories shall participate in a proficiency testing program from a provider approved as being compliant with Chapter 2 of the NELAC Standards, which is adopted by reference herein. Participation means that the laboratory will analyze and report to the approved provider the results of all proficiency test samples contained in the approved program for those categories and analytes with which the laboratory desires and maintains certification. Certified laboratories shall participate in proficiency testing at least

twice per year for all categories and analytes certified, if available.

(2) Laboratories shall bear the cost of any subscription to a proficiency testing program required by the Department of _____ for certification purposes. The Department of _____ shall not be charged a fee for the analysis of any performance evaluation samples.

(3) All analytes within each regulatory program that are certified or pending certification must be satisfactorily analyzed, if available, on two of the most recent three proficiency testing rounds attempted. A laboratory may participate in successive testing rounds where the closing dates for reporting results are greater than 30 days but less than 7 months apart. The laboratory must authorize the approved provider, prior to the testing round closing date, to submit the proficiency testing results to the Department of _____ concurrently with the submittal of these results to the laboratory; otherwise, Department of _____ may refuse to consider the proficiency test results from that round for fulfilling the requirements of this Rule.

(4) Proficiency test sample results shall be considered satisfactory when they are within the acceptance limits established by the approved proficiency test sample provider, according to one of the scoring options listed in Chapter 2, Appendix C of the NELAC Standards, which is herein adopted by reference.

(5) A laboratory that meets the requirements of subsection (3) above for a particular analyte is eligible for certification for all pending test methods for that analyte. Otherwise, certification shall be denied, suspended, or revoked for all test methods associated with that analyte.

(6) If the two failed proficiency results do not occur on consecutive testing round attempts, then certification shall be suspended and then reinstated for the same test methods suspended when the laboratory has analyzed one follow-up proficiency test sample, approved beforehand by the Department of _____, for each affected analyte and produced results within the acceptance limits established by the approved provider.

(7) A laboratory's certification for an analyte failed on two consecutive testing round attempts shall be suspended. The laboratory must then satisfactorily analyze the analyte in the next testing round attempt, or else certification is revoked for that analyte. During the six months following the suspension, if the laboratory passes the analyte in two of the latest three testing round attempts, the Department will reinstate certification for the analyte with the same test methods that were previously suspended. Otherwise, certification for the analyte shall be revoked.

(8) An applicant or certified laboratory shall establish and maintain the accuracy and reliability of its testing procedures for analytes not available in an approved proficiency testing program through a system of internal quality management.

(9) A certified laboratory shall comply with the other requirements for enrollment, testing, proper conduct, and successful participation in the approved proficiency testing program, as specified in Sections 2.4, 2.5, and 2.7 of the NELAC Standards, which are all adopted by reference herein.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.009 Quality Manual Requirements.

(1) The laboratory shall prepare and follow a written quality assurance plan. This Quality Manual shall be submitted to the Department of _____ for review prior to the on-site inspection of the laboratory.

(2) All Quality Manuals submitted to the Department of _____ for review shall comply with the specifications in Section 5.5 of the NELAC Standards and in the regulations referenced in Rules 100A-1.005(4) through 100A-1.005(10) for Regulatory Programs, which are incorporated by reference herein. The Quality Manual must cite the laboratory's objectives for sensitivity, precision, and accuracy for each pending and certified analyte and test method.

(3) A copy of the written Quality Manual, analytical methods, quality control data, proficiency test data, and other

records documenting compliance with this Rule shall be available at the laboratory for review during the on-site inspection.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.010 On-Site Laboratory Assessments.

(1) The Department of _____ is authorized to inspect the premises and operations of any certified laboratory or any laboratory seeking certification or change in certification under this Rule. After completion of all prerequisites specified in Rules 100A-1.006(4)(a) through 100A-1.006(4)(c), the Department of _____ shall conduct the on-site inspection of the laboratory to determine compliance with all the requirements in this Rule.

(2) The Department of _____ shall inspect the premises and operations of laboratories certified or seeking certification to perform analyses pursuant to this Rule. Such inspections shall occur at least once every 2 calendar years and at such other times as the Department of _____ deems necessary to determine continued compliance with this Rule. Inspections may be unannounced and may include the on-site analysis of proficiency test samples as well as the photocopying, photographing, or videotaping of any portion of the laboratory,

equipment, activity, samples in custody, records, test results, or other information related to certification under this Rule.

(3) Inspections will be unannounced only in those cases in which the Department of _____ determines this approach necessary to establish compliance. Factors such as past record, proficiency test performance, personnel, overall laboratory performance, and complaints from the public or other regulatory agencies will be considered in making this determination.

(4) On-site inspections shall be conducted in accordance with Sections 3.4 - 3.7 of the NELAC Standards, which are adopted herein by reference. Inspections of organizations that support source air monitoring and testing may also be conducted according to the "Technical Evaluation Criteria for Accreditation of Emission Testing Organizations (EPA Methods 1 through 5 and Associated Methods)," Roy F. Weston Inc., October 30, 1992, which is adopted by reference herein. Laboratories conducting wastewater testing may also be inspected according to the quality assurance criteria in "Handbook for Analytical Quality Control in Water and Wastewater Laboratories," EPA/600/4-79/019, March 1979, adopted herein by reference. Laboratories analyzing drinking water samples may also be inspected according to the criteria in the "Manual for the Certification of Laboratories Analyzing Drinking Water, Criteria and Procedures, Quality Assurance," 4th Edition, EPA 815-B-97-001, March 1997, adopted by reference herein. Inspections will include the review of quality control data. The laboratory shall conduct at least one Chemistry and

Radiochemistry laboratory control sample analysis, Whole Effluent Toxicity reference toxicant test, or Microbiology or Microscopy positive culture control test through the confirmed phase annually for each certified analyte and test method.

(5) Inspections of a laboratory may occur more frequently than once every two calendar years when there are complaints about the laboratory quality, questions of fraud, numerous or serious deficiencies from the previous on-site inspection, any of the changes noted in Rule 100A-1.006(3), or any other criteria in Section 3.3 of the NELAC Standards, adopted by reference herein.

(6) Inspections will include the on-site analysis of proficiency test samples when the Department of _____ is unable to determine compliance using more conventional methods.

(7) The laboratory shall ensure that its documented Quality System, analytical methods, quality control data, proficiency test data, laboratory standard operating procedures, and other records needed to verify compliance with Chapter 5 of the NELAC Standards, adopted by reference herein, and this Rule are available for review during the on-site laboratory inspection. The laboratory shall allow the Department’s authorized personnel to examine records; observe the laboratory’s procedures, facilities, and equipment; and interview staff as necessary to determine such compliance.

(8) The laboratory shall submit to the Department of _____ a Plan of Correction for each deficiency noted during the on-site evaluation. Form _____, "Statement of

Deficiencies and Plan of Correction," __(revision date)__ is herein incorporated by reference. This submittal is due within 30 days of the laboratory receiving the inspection report, Form _____ must be returned to the Department within this timeframe with the date and original signature of the laboratory responsible official, and each Plan of Correction must have an estimated completion date. If the Department determines that a Plan of Correction will not correct the deficiency cited, the laboratory will be notified in writing and will have 30 days to submit a revised Plan of Correction. If this revised Plan of Correction is unacceptable, or if the next on-site inspection of the laboratory shows that the deficiency has not been corrected, then the Department of _____ shall revoke or deny certification for the affected tiers of accreditation.

Specific Authority: _____
Law Implemented: _____
History: New _____

100A-1.011 Renewal of Annual Certification.

(1) The Department of _____ will renew a laboratory's certification after return of the renewal invoice on Form _____ and receipt of the renewal certification fee, provided the laboratory is maintaining compliance with this Rule, attests to such compliance on Form _____, and has reported acceptable proficiency test values for the categories and

analytes certified within the 12 months prior to July 1 of each calendar year. The Renewal Attestation of Compliance, Form _____, __(revision date)__, and Environmental Testing Laboratory Renewal Invoice, Form _____, __(revision date)__, are both herein adopted by reference.

(2) A laboratory's certification shall expire on July 1 of each calender year, unless its certification has been renewed.

(3) The Department of _____ will mail the renewal invoices and attestation forms at least 30 days prior to July 1. Failure to receive a renewal invoice does not exempt laboratories from paying the renewal certification fee.

(4) A laboratory whose certification has expired may reapply for certification in accordance with Rule 100A-1.006(1).

(5) The certified laboratory shall maintain all key accreditation elements, such as facilities, equipment, quality system documents, personnel qualifications, standards, sample handling procedures, and other elements in Section 4.3.3 of the NELAC Standards, herein adopted by reference, that originally served as the basis for the laboratory's initial certification.

Specific Authority: _____
Law Implemented: _____
History: New _____

100A-1.012 Display of Certificate.

(1) A current Certificate shall be displayed at all times in a prominent place in each certified laboratory where it may be viewed by the public. The Certificate is the property of the Department of _____ and must be returned to the Department if the laboratory's entire certification is revoked, if the laboratory withdraws from the certification program, or if the Department's status as a NELAP Accrediting Authority changes. Form _____, __(revision date)__, "NELAP Testing Laboratory Certificate," is adopted by reference herein.

(2) The certified laboratory shall also receive an Analyte Sheet that shows all categories, analytes, and test methods for which the laboratory is certified. The Analyte Sheet will be updated each time the laboratory's scope of certification has changed. Form _____, __(revision date)__, "National Environmental Laboratory Accreditation Program Analyte Sheet," is adopted by reference herein.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.013 Contractual Agreements, Records, and Reports.

(1) Laboratories performing analytical work under certification auspices shall guarantee analytical performance according to Chapter 5, Appendix D of the NELAC Standards, adopted by reference herein, for those analytes and test methods

with which they have been certified. Each certified laboratory shall maintain the documentation required in Chapter 5 of the NELAC Standards, adopted by reference herein, for at least 5 years.

(2) SPECIFIC STATE REPORTING REQUIREMENTS:_____

_____

(3) For reporting of results, the laboratory shall comply with the laboratory report format and content requirements in Section 5.13 of the NELAC Standards, adopted herein adopted by reference.

(4) A laboratory may subcontract analytical work for those analytes, categories, and test methods which the laboratory is not certified to perform, provided that it advises the client in writing of its intention to subcontract a portion of the testing and fulfills the requirements of Section 5.14 of the NELAC Standards, adopted by reference herein. The primary laboratory is responsible for determining that the contracted laboratory has been certified pursuant to this Rule for the appropriate categories, test methods, and analytes for which it is being contracted to perform. Records at the primary laboratory shall include the sample analysis reports issued from each contract laboratory. All data reports issued by the primary laboratory that contain results reported by one or more contract laboratories shall include the certification number of each contract laboratory. The primary laboratory shall unambiguously identify in its reports which test results were produced from its

laboratory analyses and the results obtained from each contract laboratory.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.014 Denial or Revocation of Certification.

(1) The Department of _____ is authorized to deny, suspend, limit, or revoke the certification of any laboratory on any of the following grounds:

(a) Making false statements on an application, sample analysis report, or on any document associated with certification in violation of Rules 100A-1.006, 100A-1.007, and 100A-1.013.

(b) Making consistent errors in field sampling or laboratory testing, or erroneous reporting, in violation of Rules 100A-1.005 and 100A-1.013.

(c) Falsifying the results of laboratory testing, or misrepresenting any information from field sampling that is critical for demonstrating regulatory compliance, in violation of Rules 100A-1.005 and 100A-1.013.

(d) Failing to employ approved sampling protocols or testing methods in the performance of laboratory activities for which certification is required, or failing to notify clients of method modifications, in violation of Rules 100A-1.003 and 100A-1.005.

(e) Failing to maintain facilities or equipment according to the laboratory's quality assurance plan, documented Quality System, approved test methods, or regulatory program mandates, in violation of Rules 100A-1.005 and 100A-1.009.

(f) Failing to report analytical test results in the required format, reporting results without using appropriate data qualifiers and without disclaiming certification auspices, or not maintaining required records of test results, in violation of Rules 100A-1.005 and 100A-1.013.

(g) Failing to participate successfully in an approved proficiency testing program when available, in violation of Rule 100A-1.008.

(h) Failing to comply with the required quality assurance program, in violation of Rules 100A-1.005 and 100A-1.009.

(i) Violating or assisting in the violation of any provision of Rules 100A-1.001 through 100A-1.017.

(j) Falsely claiming certification credentials for those test methods and analytes with which the laboratory is not certified, in violation of Rule 100A-1.013.

(k) Failing to correct deficiencies within the time indicated in the approved plan of correction, in violation of Rule 100A-1.010(7).

(l) Failing to pay initial certification or renewal certification fees or expenses incurred by the Department of _____ as a result of inspecting an out-of-state laboratory as stipulated in Rule 100A-1.017(5) and in violation of Rule 100A-1.007(4).

(m) Failing to indicate clearly when analyses were subcontracted to a certified laboratory in violation of Rule 100A-1.013(2).

(n) Failing to respond with a plan of correction to deficiencies noted by the Department of _____ on Form _____ within 30 days, in violation of Rule 100A-1.010(8). The Statement of Deficiencies and Plan of Correction, Form _____, __(revision date)__, is herein adopted by reference.

(o) Failing to report to the Department of _____ any of the changes stipulated in Rule 100A-1.006(3).

(p) Failing to analyze Quality Control Samples for each certified analyte and methodology annually in violation of Rule 100A-1.010(4).

(q) Permitting unqualified personnel to perform analyses in violation of Rule 100A-1.005(1).

(r) Communicating and receiving communication about proficiency test sample results from any other participating laboratory or facility, prior to the closing date of the relevant study, or reporting proficiency test sample results generated at another laboratory facility as its own, in violation of Rule 100A-1.008(9).

(s) Receiving any portion of another participant's proficiency test sample, or sending any portion of a proficiency test sample to another laboratory or facility, prior to the closing date of the relevant proficiency study, in violation of Rule 100A-1.008(9).

(t) Failing to admit authorized Department of _____ personnel into the laboratory facility for the on-site inspection; failing to allow the Department's personnel to examine records, interview staff, or observe the laboratory's facilities, equipment, and procedures; or failing to provide the information necessary to determine compliance with all the requirements of this Rule, in violation of Rule 100A-1.010.

(u) Committing other violations specified in Sections 4.1.4(d) and 4.4 of the NELAC Standards, which are adopted by reference herein, or misrepresenting any material fact pertinent to receiving or maintaining certification.

(2) In determining the denial, revocation, suspension or limitation, the Department of _____ will consider such factors as the gravity of the offense, the danger to the public of the offense, the intent of the violation, the extent of the violation, and the proposed correction of the problem.

Specific Authority: _____
Law Implemented: _____
History: New _____

100A-1.015 Administrative Hearings.

(1) The Department of _____ shall take agency action in accordance with __(state regulations)___ and shall afford a person whose substantial interests are affected an

opportunity for an administrative hearing in accordance with ___(state regulations)___.

(2) The Department of _____ is authorized to issue an emergency order immediately suspending the certification of a laboratory when it determines that any condition in the certified laboratory presents a clear and present danger to public health and safety.

Specific Authority: _____
Law Implemented: _____
History: New _____

100A-1.016 Recertification.

Recertification after the original certification has been revoked, or reconsideration for certification after an application has been denied, shall require submission of a new application as required for initial certification in Rule 100A-1.006(1), after the designated time period specified in Section 4.4 of the NELAC Standards, which is adopted herein by reference. A new application shall not be required for a laboratory whose certification has been suspended for a temporary period and then reinstated after the deficiencies have been corrected.

Specific Authority: _____
Law Implemented: _____
History: New _____

100A-1.017 Fees.

(1) ___(State regulations)___ authorizes the Department of _____ to charge and collect fees for the evaluation and certification of laboratories pursuant to this Rule.

(2) A nonrefundable application fee of _____ shall accompany each application. Such fee shall be assessed each subsequent application for additional analytes. The Department of _____ shall not retain this fee in circumstances where the application is not processed.

(3) In addition to the application processing fee, each laboratory shall pay to the Dapartment of _____ the following fees for the initial certification and __(time period)___ renewal for each category of certification as follows:

_____

_____

_____

_____

_____

_____

(4) The Department of _____ shall assess the expenses it incurs as a result of on-site inspection to the out-of-state laboratories, in addition to the application and certification fees in subsections (2) and (3) above.

(5) These fees are sufficient to meet the costs incurred by the Department of _____ in administering this certification program under the NELAC Standards adopted by reference herein.

Specific Authority: _____

Law Implemented: _____

History: New _____